



January 31, 2005

Food & Drug Administration  
Office of Special Nutritionals (HFS-450)  
Center for Food Safety and Applied Nutrition  
200 C Street SW  
Washington, DC 20204

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Dear Sirs:

Notice is hereby given pursuant to the requirement of section 403(r)(6)(21 U.S.C. 343(r)(6)) of the Federal Food, Drug and cosmetic Act and in accordance with the requirements of 21 CFR 101.93 that LaneLabs USA, Inc., 25 Commerce Drive, Allendale, NJ 07401 is marketing a dietary supplement bearing the following statement(s) on the label and/or in the labeling:

**TEXT OF CLAIM:**

"Helps promote balance in your digestive system by increasing the population of helpful bacteria – microorganisms that help you break down the food you eat."

"One capsule of GI48 has a special strain of Lactobacillus Fermentum PCC™ which provides a minimum of 2 billion live organism that have been clinically shown to keep working for up to 48 hours"

"The every other day probiotic"

"90% viability through stomach acid"

"This strain is so tough, it can not only survive the harsh conditions inside the digestive tract, but in clinical studies it has demonstrated its ability to adhere to GI tract cells, multiply, and remain viable (alive) for at least 48 hours after taking a single pill"

**"NAME OF INGREDIENTS:**

Lactobacillus Fermentum P.C.C.

Other Ingredients: Gelatin, Microcrystalline Cellulose, Silicon Dioxide (Flow Agent) and Stearic Acid.

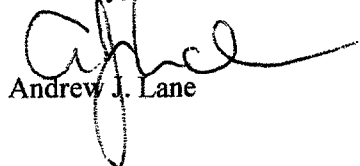
No added Salt, Yeast, Gluten, Wheat, Milk, Derivatives, Preservatives, Artificial Colors, Flavors or Sweeteners.

**NAME OF SUPPLEMENT:**

GI48™

I certify that the information contained in this notice is complete and accurate and that LaneLabs USA, Inc. has substantiation that the statements are truthful and not misleading.

Sincerely,



Andrew J. Lane

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LaneLabs - USA • LaneLabs International • Lane Medical • Lane Malignancy Testing • Anti-Aging Physicia

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